

REMARKS

Claims 37-58 are pending in the present application. Claims 49-58 were previously withdrawn from consideration as drawn to a non-elected invention, and claims 1-36 have been canceled. By virtue of this response, claims 37 and 43 have been amended, and claim 42 has been canceled. Accordingly, claims 37-41, 43-48 are currently under consideration. Amendment and cancellation of certain claims is not to be construed as a dedication to the public of any of the subject matter of the claims as previously presented.

Claim Rejections under 35 USC § 112

Claim 37 stands rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement. Specifically, the Examiner asserts that the subject matter in claim 37 is not described in the specification “in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.”

Applicants respectfully disagree with this rejection. The subject matter and limitations of claim 37 is described with sufficient detail throughout the originally-filed specification. Claim 37 recites a tethered clip assembly that has a first and a second deployed configuration, and in both deployed configurations, the at least two clips are in a closed tissue-piercing position. In the second deployed configuration, the tethered clip assembly is under longitudinal tension, and the distance between the clips is reduced from the first deployed configuration. In at least paragraphs [0119], [0122], and Fig. 12, the specification describes or teaches clips in a closed tissue-piercing position when the clips are in both deployed configurations. The specification describes reducing the distance between at least two clips in at least paragraphs [0014] and [0030]. As such, it would be clear to one of ordinary skill in the art that Applicants had possession of the device of claim 37 at the time the application was filed, and thus a rejection under 35 U.S.C. §112, first paragraph is improper.

Furthermore, Applicants note that the currently pending claims are directed to the currently elected species. On August 12, 2007, in response to a July 12, 2007 Restriction Requirement, Applicants elected claims 37-48, which are “drawn to a device for applying at least one clip.” Claim 37, which recites a “device for applying a tethered clip assembly to annular tissue,” is clearly drawn to a device for applying at least one clip. Additionally, claim 37 is also drawn to a device that includes “at least one clip [that] is configured to penetrate tissue.” Indeed, claim 37 recites clips that “are in a closed tissue-piercing position.” Because placing the clips in a closed tissue-piercing position entails piercing tissue with the clips, the clips are necessarily configured to penetrate tissue.

For at least the reasons presented above, Applicants request that the rejection of claim 37 under the first paragraph of 35 U.S.C. §112 be withdrawn.

Claim Rejections under 35 USC § 102(b)

Claims 37-44 stand rejected under 35 U.S.C. §102(b) as allegedly anticipated by U.S. Patent No. 5,984,933 to Yoon (“Yoon”). Applicants respectfully disagree with this rejection. Yoon fails to teach or disclose each and every element of amended independent claim 37, from which all remaining rejected claims depend.

Specifically, claim 37 recites a tethered clip assembly with clips that comprise “two tissue-piercing legs joined by a loop.” Yoon does not teach or disclose such a limitation. Rather, Yoon teaches a device for suturing tissue that uses “a single, plastically deformable knotting element to form a knot between opposite ends of a stitch of filamentous suture material, and, further ... a plurality of such knotting elements ... to form a plurality of stitches in tissue.” *See col. 3, ll. 6-12.* Even if the plurality of knotting elements described in Yoon could be characterized as a “tethered clip assembly,” which Applicants do not concede, none of the disclosed knotting elements comprise two legs joined by a loop. *See FIGS. 1, 2, 8-16, 44, and 48.* Additionally, claim 37 recites that a tether “passes through the loop transversely to the legs.” Because Yoon does not teach or disclose a

knotting element having two legs joined by a loop, it cannot teach or disclose a tether passing through the loop transversely to the legs.

Additionally, claim 37 recites that the clips have “a closed tissue-piercing position.” Yoon fails to teach or disclose such a limitation. As mentioned above, the Yoon device is intended to suture tissue, and only contemplates piercing tissue with the suture or a needle attached thereto. Yoon’s knotting elements are specifically configured to engage suture, not tissue. Each knotting element has a grasping site that is “a location at which the knotting element non-releasably engages the suture material to form a stitch such that a knotting element has the effect of tying a knot in a length of suture material.” See col. 7, l. 66-col. 8, l. 2 (emphasis added). These knotting elements are “positioned adjacent to the tissue at the entry point.” See col. 3, ll. 53-55. If the knotting elements are positioned adjacent to tissue, they are not placed such that they are piercing tissue. It is clear that these knotting elements are not positioned, configured, modified, or otherwise intended to pierce tissue, and nowhere does Yoon either teach or disclose using, configuring, or otherwise modifying any of the knotting elements to pierce tissue.

If Yoon’s knotting elements were capable of piercing tissue, it would render Yoon’s device inoperable for its intended purpose. See, MPEP § 2143.01(V)-(VI). As noted above the knotting elements are closed and locked to “non-releasably” engage suture to have the “effect of tying a knot in a length of suture.” See col. 7, l. 66-col. 8, l. 2. If tissue were to be placed in the grasping site of a knotting element, as would occur if the knotting element were used to pierce tissue, the knotting element would not be able to close and lock to engage a suture. For example, if tissue were to be placed in grasping site **2226** of the knotting element **2220** shown in FIG. 44, jaws **2238** and **2240** would be unable to close down sufficiently for locking protrusion **2239** and locking lip **2241** to lock the knotting element in a closed configuration. As such, it would be particularly disadvantageous to configure the Yoon knotting elements to pierce tissue.

Furthermore, claim 37 also recites that “at least one clip is slidable on the tether when the tethered clip assembly is in both its first and second deployed configuration.” Yoon does not teach or disclose such a limitation. Indeed, the “knotting elements” of Yoon are not slidable over a tether

when the knotting elements are deployed. The Yoon knotting elements include attachment points “at which the knotting element is carried by the suture material.” See col. 7, ll. 63-65. While the attachment point may “slidably or fixedly” receive a length of suture when the knotting element is open, “once the knotting element is closed, the suture material passing through the knotting elements at attachment sites 19” will be gripped by the knotting element such that the knotting element will be in a fixed position along the suture material.” See col. 5, ll. 18-20; col. 9, ll. 15-19 (emphasis added). This fixed positioning is necessary for the knotting element to act as a knot.

Similarly, claim 37 recites that a first distance between two clips is “reduced to a second distance” when the tether is “under longitudinal tension” and in its second deployed configuration. Yoon does not teach or disclose such a limitation. As noted immediately above, the Yoon knotting elements are locked in place once they have been closed, and thus the distance between knotting elements will not change when the Yoon suture is placed under tension. Applicants respectfully disagree with Examiner’s assertion that this limitation is inherent in Yoon. Inherency can only be established on a basis of fact and/or technical reasoning to support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art. See MPEP 2112. Because the Yoon knotting elements may be locked in place along the suture, the distance between elements will not necessarily change when the suture is placed under tension. The Examiner even concedes that the criteria for inherency have not been met in stating “[t]he examiners position is when the tether of Yoon is under tension the distance will be reduced, under certain usage the distance of the clips would inherently occur.” See January 12, 2009 Office Action, page. 6. If the distance between clips changes under tension only “under certain usage,” it does not necessarily change, and thus is not inherent.

For at least the reasons stated above, Yoon does not teach or disclose each and every limitation of claim 37, from which all remaining rejected claims depend. As such, the rejections under 35 U.S.C. §102(b) of the currently pending claims cannot stand. Therefore, Applicants respectfully request that the rejections of claims 37-44 under 35 U.S.C. §102(b) be withdrawn.

Claim Rejections under 35 USC § 103(a)

Claims 45, 46, and 48 stand rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Yoon, in view of U.S. Patent No. 5,524,630 to Crowley ("Crowley"). Claim 47 stands rejected under 35 U.S.C. 103(a) as allegedly unpatentable over Yoon and Crowley, further in view of U.S. Patent No. 5,766,240 to Johnson ("Johnson").

Applicants disagree with these rejections. Yoon was discussed in detail above with respect to claim 37, where it was established that Yoon fails to teach or disclose clips having two tissue-piercing legs joined by a loop and having tissue-piercing configurations, fails to teach or disclose at least one clip slidable along a tether when a tethered clip assembly is in its deployed configurations, and fails to teach or disclose a reduction of distance between clips when the tether is placed under longitudinal tension. Crowley and Johnson fail to cure these deficiencies. As such, Applicants respectfully request that the rejection of claims 45-48 under 35 U.S.C. §103(a) be withdrawn.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

Any remarks in support of patentability of one claim should not be imputed to any other claim, even if similar terminology is used. Additionally, any remarks referring to only a portion of a claim should not be understood to base patentability on that portion; rather, patentability must rest on each claim taken as a whole. Applicants respectfully traverse each of the Examiner's rejections and each of the Examiner's assertions regarding what the prior art shows or teaches, even if not expressly discussed herein. Although amendments have been made, no acquiescence or estoppel is or should be implied thereby. Rather, the amendments are made only to expedite prosecution of the present application, and without prejudice to presentation or assertion, in the future, of claims on the subject matter affected thereby.

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicants are not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicants reserve the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child, or related prosecution history shall not reasonably infer that Applicants have made any disclaimers or disavowals of any subject matter supported by the present application.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket no. 578492000510. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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